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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

WARNING LETTER

NWE-07-99W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

February 8, 1999

Paul DiMare, President
DiMare Seafoods Co., Inc.
585 North Shore Road
Revere, MA 02151

Dear Mr. DiMare:

On October 20 - 22, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 585 North Shore Road, Revere, MA 02151. The investigators documented violations of Section 402 (a)(4) of the Federal Food Drug and Cosmetic Act and Title 21, Code of Federal Regulations (21CFR) Parts 110 "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food" (GMPs) and 123 "Safe and Sanitary Processing and Importing of Fish and Fishery Products" (Seafood HACCP Regulation), as follows:

- Monitoring record data are missing (21 CFR 123.6(c)(7). For example, your firm's HACCP plan for cooked lobstermeat states that internal product temperatures will be taken during the cooling step. This is part of your monitoring procedure. However, during the inspection our Investigators observed that this was not done. No temperatures were taken and estimated values were written on the log *after* processing had taken place.

- An appropriate critical limit is not listed in the plan, 21 CFR 123.6(c)(3). For example, your firm's HACCP plan for cooked lobstermeat states that the

lobstermeat should reach an internal temperature of [redacted]. However, only the final cook temperature is recorded. There is no record of come-up time or actual time above [redacted]. Without a time limit set for the cook process, your firm does not have any assurance that this critical temperature is reached for the whole lot.

- Sanitation monitoring is inadequate, 21 CFR 123.11(b). For example, there were numerous sanitation deficiencies observed during the inspection and listed on the FDA 483, which was discussed with you at the conclusion of the inspection.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

FDA will not issue any certicicates of export for any of the seafood products processed at your facility until your firm is fully in compliance with the seafood HACCP regulations. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 279-1675, Extension 113.

Sincerely,

John Marzilli
District Director
New England District Office